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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,706	09/11/2003	Simon L. McGurk	029318-0968	4753

31049 7590 04/10/2006

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EXAMINER	
VANIK, DAVID L	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,706	MCGURK ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *9-11,23,29 and 44-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12-22,24-28 and 30-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/30/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Response to Election/Restriction filed on 1/20/2006.

Election/Restrictions

Applicant's election with traverse of Claims 1-43 in the reply filed on 1/20/2006 is acknowledged. The traversal is on the ground(s) that searching Groups I-III does not present the examiner with a search burden. This is not found persuasive because Groups I-III differ in scope as indicated by their distinct classification. Additionally, the restriction is proper because the product as claimed can be made and used in materially different manners than the ones set forth in the instant Groups II-III. However, it should be noted that, should the product claims be deemed allowable, the restriction requirement concerning Groups II – III will be withdrawn. As a result of Applicant's election of Group I together with an election the species, claims 9-11, 23, 29, 44-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/20/2006. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12-22, 24-28, 30-43 rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/18374 ('374).

'374 disclose nanoparticle-based compositions comprising the following: (1) a poorly soluble agent having an effective particle size of less than about 1000nm; (2) at least one surface stabilizer; and (3) at least one rate-controlling polymer (Claim 1). Like the instant application, the drug can be crystalline and may comprise analgesic agents (page 4, lines 5-31 and page 10, lines 1-31). In terms of amounts, the nanoparticle agent in combination with the surface stabilizer can be present in an amount between about 5% to about 95%, the rate-controlling polymers can be present between about 5% to about 95%, and water can be present between the range of 5% to about 97% (See page 15, line 19 – page 16, line 4 and Examples 1-17). According to '374, the surface stabilizers can be chosen from a long list of compounds, including nonionic surfactants, and the rate-controlling polymers can include guar gum and gelatin (page 11, line 9 – 24 and page 13, line 18 – page 14, line 10).

It is the examiner's position that, inherently, the composition advanced by '374 has T_{max}, C_{max}, and AUC parameters that meet the imitations of the instant claims 31-36. Moreover, it is the examiner's position that the compositions advanced by '374 exhibits gelation sufficient to retain excess water in the solid or semi-solid state and does not produce significantly absorption levels when administered under fed as compared to fasting conditions. Since the essential elements of the '374 composition are identical to the instant compositions (that is, (1) a poorly soluble agent having an effective particle size of less than about 1000nm; (2) at least one surface stabilizer; and (3) at least one rate-controlling polymer), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '374 anticipates the compositions enumerated in the instant claim set.

Claims 1-4, 6-8, 12-22, 24-28, 30-43 rejected under 35 U.S.C. 102(a) as being by anticipated by US 6,316,029 ('029).

'029 disclose rapidly disintegrating solid oral dosage forms of a poorly soluble drug (abstract). Like the instant application, the composition comprises the following: (1) a solid dosage matrix comprising a water-soluble excipient; (2) a poorly soluble active agent having an effective particle size of less than 2000 nm, (3) and at least one surface stabilizer (Claim 1). The poorly soluble drug can be crystalline and may

comprise analgesic agents (column 4, line 4 and column 6, line 52). In terms of amounts, the nanoparticle agent in combination with the surface stabilizer can be present in an amount between about 0.1 to about 99% and the water-soluble excipient can be present between about 0.1% to about 99.9% (column 9, line 55-67). According to '029, the surface stabilizers can be chosen from a long list of compounds, including nonionic surfactants, and the water-soluble excipients can include gelatin or dextran (column 7, line 28 – 67 and column 8, line 41 – column 9, line 27).

It is also the examiner's position that, inherently, the composition advanced by '029 has T_{max}, C_{max}, and AUC parameters that meet the imitations of the instant claims 31-36. Moreover, it is the examiner's position that the compositions advanced by '029 exhibits gelation sufficient to retain excess water in the solid or semi-solid state and does not produce significantly absorption levels when administered under fed as compared to fasting conditions. Since the essential elements of the '029 composition are identical to the instant compositions (that is, (1) a solid dosage matrix comprising a water-soluble excipient; (2) a poorly soluble active agent having an effective particle size of less than 2000 nm, (3) and at least one surface stabilizer), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '029 anticipates the compositions enumerated in the instant claim set.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615

4/4/06

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PRIMARY EXAMINER
GROUP 1500